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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
GRASER, JENNIFER E	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/26/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/844,281	MANGOLD ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgment and entry of the Amendment submitted on 12/4/06 is made. Claims 66-85 are currently pending.

Claim Rejections - 35 USC § 112-2nd paragraph

2. Claims 66-77 and 79-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 66, 69 and 79 are vague and indefinite due to the phrase "specifically binds spores or vegetative cells of B.anthracis *relative to* the spores or vegetative cells of B.thuringiensis, etc...". The term "relative to" is defined as "with regard to; concerning, e.g., questions relative to the deficit. Having pertinence or relevance; connected or related.

http://www.answers.com/topic/relative American Heritage Dictionary. Defines relative as:

1. Considered in comparison with something else: *the relative quiet of the suburbs*
2. Having pertinence or relevance; connected or related.

Accordingly, it is unclear what is intended by this language. This language does not convey that the isolated antibody or fragment only binds B.anthracis and not the other spores or vegetative cells.

Response to Applicant's Arguments:

Applicants argue that the language of the claims must be read in the context that they are presented. They argue that the term "relative to" is not used in a vacuum or in an ambiguous fashion. They argue that the feature is the activity of the antibody or fragment which "specifically binds" a first group of entities or vegetative cells of B.anthracis "relative to" a second group of entities (the spores or vegetative cells of B.thuringiensis, B.cereus, B.globigii and B.licheniformis). It is argued that a practitioner in the art would understand that a monoclonal antibody, or fragment thereof, is considered to have "some level of binding specificity" and that a skilled person would understand that a level of binding specificity is "relative" in that the antibody would bind one or more entities while not binding one or more others by comparison. These arguments have been fully and carefully considered but they are not deemed persuasive. The arguments presented in the reply, e.g., a monoclonal antibody, or fragment thereof, is considered to have *"some level* of binding specificity", the antibody would bind one or more entities while not binding one or more others by comparison", supports the argument that the claims are ambiguous. The claims should clearly state that the the isolated antibody or fragment only binds B.anthracis and ***not*** the other spores or vegetative cells. The term 'relative' is ambiguous and the arguments, e.g., *"some level* of binding specificity", the antibody would bind one or more entities while not binding one or more others by comparison", makes it unclear whether the term "relative" is used to indicate that the claimed monoclonal antibody/fragment has good

binding specificity for B.anthracis spores or vegetative cells, but may also weakly bind the spores or vegetative cells of B.thuringiensis, B.cereus, B.globigii and B.licheniformis or whether it does not bind the second group of bacterial spores/cells at all. The claims as they stand are vague and indefinite.

With respect to claims 66, 69 and 79 the amino acid sequence of EA1, e.g., SEQ ID NO:1 or the deposited antibody, should be inserted in the claims. The mere recitation of a name, i.e., EA1, to describe the invention is not sufficient to satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. The claim should provide any structural properties, such as the amino acid sequence of the protein or molecular weight, which would allow for one to identify the protein without ambiguity. The mere recitation of a name does not adequately define the claimed antibody. The antigen to which the antibody binds is a critical limitation. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Response to Applicants Arguments. Applicants argue that claim 73 recites SEQ ID NO:1 so it should not be included in this rejection. It is noted that the rejection recites claims "66, 69 and 79" and does not single out claim 73. Claim 73 is included in the overall rejection since it does not cure the deficiencies in relation to the term "relative to". Applicants also argue that the skilled person would be apprised of

relevant background information regarding EA1 polypeptide, or protein, from B.anthracis. They cite prior art references on page 12 of the response. It is stated that each of these references recite that EA1 antigen is recognized as a distinct entity in comparison to other components or parts of B.anthracis. They argue that the references describe that the polyclonal antibodies which bind to EA1 are cross-reactive with both B.thuringiensis and B.cereus. They argue the references teach the amino acids sequence of the EA1 antigen and its purification and characterization. These arguments have been fully and carefully considered but are not deemed persuasive. Applicants have stated that they have discovered epitopes of the EA1 antigen which can be used to generate antibodies which can specifically identify B.anthracis apart from other Bacillus organisms, such as B.cereus or B.thuringiensis. The rejection remains because the claims fail to teach these specific epitopes or claim the structure of these antibodies which bind them. A deposit of these antibodies would cure this deficiency.

Claim Rejections - 35 USC § 112-Scope of Enablement

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 66-77 and 79-85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "monoclonal antibody AX-EA1-G1 which was deposited with the ATCC and accorded accession number PTA-2632, on October 26, 2000 and shown to have strong reactivity against B. anthracis antigens and negative

reactivity against the closely related strains of B.thuringiensis (ATCC 33680, HD571, A1 Hakam, and commercial insecticide preparation from Dipel Dust), B. globigii and B. licheniformis (ATCC 25972) (Table 2, 3 and 4)". [The specification also recites that three monoclonal antibodies (termed AX-EA1- G1, 8G4, and 9F5) were selected for their ability to uniquely detect B. anthracis and not cross-react with other closely related Bacillus species; however it does not appear that deposit was made of these 3 antibodies and therefore, until Deposit requirements are met, the specification is only enabled for the monoclonal antibody designated as PT-2632], does not reasonably provide enablement for the broad scope of the claims which include antibodies outside of the deposited antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Deposit Requirements have been met for monoclonal antibody AX-EA1-G1 which was deposited with the ATCC and accorded accession number PTA-2632, on October 26, 2000 (See Applicants' Response 7/20/06). Applicants have stated on page 11 of the response dated July 20, 2006 that the invention is based on the discovery that there are epitopes of the EA1 polypeptide that may be used to specifically identify B.anthracis apart from other organisms such as, B.cereus or B.thuringiensis. They state that the discovery was based upon antibodies that bind epitopes found on B.anthracis and not on other Bacillus species and they cite paragraphs 0036 to 0039 and Tables 1-4 as examples. They state that since the antibodies were found on the EA1 polypeptide of B.anthracis, they were described as binding the EA1 polypeptide. They do note that the

antibodies may bind other Bacillus organisms such as to the OlpA polypeptide of B.licheniformis.

The instant claims are drawn to the discovered invention, but encompass antibodies which have not been discovered. The novel epitopes or the antibodies are not structurally recited in the claims. The functional limitations are not enough to allow one to identify the structure which is being claimed. The scope of the claimed invention is much broader than what is taught in the instant specification. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." The claims should be amended so that the antibodies are claimed by deposit information. The claims could also be amended to recite the specific epitope, by SEQ ID NO. to which the antibodies bind, provided there is support in the instant specification. It appears that the top of page 14 of the instant specification recites that, it can be concluded that the epitope to which AX-EA1-G1 binds is located somewhere

within amino acids 181-833. However, it does not appear that this information would be sufficient to enable anything broader than the deposited antibodies.

Response to Applicants' Arguments:

Applicants have argued that they asserted that the antibodies of the Mesnage et al document would be expected to bind to the OlpA polypeptide of B.licheniformis yet there is no structure recited in the instant claims which would distinguish the claimed antibodies from the antibodies taught by Mesnage et al. Applicants argue the novelty and unexpected discovery of an antibody which binds specifically to epitopes which render the antibody specific over the monoclonal and polyclonal antibodies known in the prior art, yet the novel, unexpected antibody is not structurally claimed. The claims do not recite the novel discovery. The claims attempt to claim the antibody by functional characteristics. However, it does not appear that the monoclonal antibodies would be reproducible.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 66-77 and 79-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mesnage et al (Molec. Microbiol. 1997, 23(6): 1147-1 155), in view of

Kohler et al (Science. 1986. 233: 1281-1285) and further in view of Loomis et al (WO 99/64863).

Mesnage et al teach isolated antibodies to the Bacillus anthracis S-layer component, **EAI**. The major cell antigen to which the isolated antibodies bind in the Mesnage reference is 100% identical to the EAI protein disclosed by Applicants and set forth in SEQ ID NO: 1. It is disclosed that EAI constitutes the main lattice of the B.anthracis S-layer, and is the major cell-associated antigen. See abstract. Antibodies to the surface array protein (Sap) are also taught. It is taught that a Western blot assay suggested that the antibodies were highly specific to B.anthracis and did not cross-react. See page 1150-1151. Electron microscopy using grids with rabbit anti-EAI antibodies or rabbit anti-sap antibodies, or on anti-sap antibodies. The grids were incubated on colloidal gold anti-rabbit or anti-mouse coupled antibodies. The Western blots and grids performed with the EA1 antibodies anticipate the method of claim 64 as they include contacting an antibody/fragment with a sample, forming a complex and detecting said complex. The major cell antigen to which the isolated antibodies bind in the Mesnage reference is 100% identical to the EAI protein disclosed by Applicants. However Mesnage et al do not specifically recite that the antibodies may be monoclonal antibodies.

Kohler et al teach that making monoclonal antibodies to known antigens was common and have greater specificity than polyclonal antibodies and can be readily produced in great quantities.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that monoclonal antibodies to the EA1 antigen could be generated/used in place of polyclonal antisera because it was well known in the prior art as evidenced by Kohler that, in general, monoclonal antibodies have proven superior to polyclonal antisera both in terms of production and clinical utility. Polyclonal antisera are not only costly and labor intensive to produce, but they are also difficult to quality control because each immunized rabbit can produce only so much antisera and every new rabbit is different. Therapeutically monoclonals can more precisely impact a target, often with fewer adverse effects and greater specificity. Accordingly, one of ordinary skill in the art would have been motivated to make monoclonal antibodies to the EA1 antigen.

Applicants have disclosed in the instant specification that antibodies directed against this EAI protein are antibodies which bind to B.anthracis, but do not bind to B.thuringiensis, B.cereus, B.globigii and B.lichenformis. These antibodies are disclosed as the preferred embodiment in the instant specification. Although the combination of prior art references do not specifically recite that the antibody to B.anthracis does not specifically react with B.thuringiensis, B.cereus, B.globigii and B.lichenformis, it inherently would not since the antigen to which it binds is specific to B.anthracis and the instant specification supports this finding. The monoclonal antibodies to the EAI protein would be identical to Applicant's antibodies to the EAI antibody, i.e., the antibodies are raised against the same antigen. There are no structural differences between the prior art antibody, e.g., specifically binds EA1 antigen of B.anthracis, and those that are instantly claimed. The intended use of the claimed composition does not patentably

distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition; e.g., does not bind *B.thuringiensis* or *B.cereus*. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since the Patent Office does not have the facilities for examining and comparing Applicant's antibody with the antibody of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 19&&). The instant kit claims recited in claims 66 and 70-77 do not require any components other than the antibodies, the reference anticipates the claims. The phrase "diagnostic kit" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. However, if this is not deemed persuasive, it is set forth that the secondary reference provides motivation to assemble the antibody and detection system as a 'kit' as outlined below.

Mesnage et al does not particularly exemplify the use of these antibodies in a colloidal particle based lateral flow detection system.

Loomis et al teach that colloidal gold particle immunoassays have been successfully used in the prior art for many years. See pages 1-3. Loomis et al teach a more sensitive immunoassay test to what was known in the art. It is a colloidal colorimetric flow through and lateral flow assay. The entire test is conducted on a test strep and the detection antibody is preferably a FAB fragment that has been labeled with a 5O-100mm gold particle and immobilized on a test pad. See page 4. It is taught that the use of capture dendrimers to align and secure capture antibodies on a solid surface insure that no immunological activity of the capture antibody is sterically hindered. Loomis claims the assay as a "test system".

It would have been prima facie obvious to one of ordinary skill in the art to use the antibodies taught by Mesnage et al in a colloidal lateral flow detection system as taught by Loomis et al to detect B.anthracis because Mesnage et al teach that the antibodies are highly specific to B.anthracis and that EAI constitutes the main lattice of the B.anthracis S-layer, and is the major cell-associated antigen. One of ordinary skill in the art would have a reasonable expectation that a specific antibody developed against the major cell-associated antigen of a bacterium to be very effective in detecting the bacterium in a sample. Loomis et al teaches that it is a highly sensitive detection assay which is simple, sensitive and specific. The use of the EAI and/or Sap antibodies taught by Mesnage in a colloidal lateral flow detection system would have been obvious as a B.anthracis detection system. The assembly of the reagents to these assays in a diagnostic kit would have been obvious to one of ordinary skill in the art at the time the invention was made for convenience and storage capabilities. Loomis claims the assay

as a "test system". It would have been obvious to one of ordinary skill in the art at the time the invention was made that this test system, if not an actual kit itself, could have been assembled as a kit because kits comprising detection assays were very well known in the prior art at the time the invention was made and the motivation for providing the reagents in kit would have been commercial as well as for ease in having all of the reagents present in one place.

Response to Applicants' Arguments:

The instant specification only recites that the claimed antibody binds to an epitope somewhere amino acids 181-833. The EA1 protein is 833 amino acids in length. It appears that Mesnage's antibody binds somewhere within those amino acids as well, absent specific structural evidence to the contrary. It is irrelevant that Mesnage do not provide cross-reaction studies against B.thuringenienis or B.cereus, the antibodies are structurally the same to that which is claimed and, therefore, would inherently possess the same binding capabilities. Applicants argue that the intended use of their antibodies 'does not bind B.thuringiensis or B.cereus' is enough to distinguish over the prior art of record. This is not deemed persuasive. There are no structural differences between the prior art antibody, e.g., specifically binds EA1 antigen of B.anthracis. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The intended use of the claimed composition does not patentably distinguish the composition, *per se*, since

such undisclosed use is inherent in the reference composition; e.g., does not bind *B.thuringiensis* or *B.cereus*. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. There is nothing in the claims which distinguishes the structure of the antibody with the antibodies taught by Mesnage. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.

Additionally, Mesnage specifically teach that a Western blot assay suggested that the antibodies (to EA1) were highly specific to B.anthracis and did not cross-react. See page 1150-1151.

Since the Patent Office does not have the facilities for examining and comparing Applicant's antibody with the antibody of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 19&&).

It is especially noted that the instant claims allow for fragments of antibodies as well and do not require the antibody to bind to any specific epitope along the EA1 polypeptide. The language of the instant claims allow for the antibody to bind to any epitope or epitopes of the EA1 antigen. The antibody taught by Mesnage binds to an antigen which is 100% identical to the antigen to which Applicants' antibody binds.

Accordingly, since the antibodies claimed are structurally the same, e.g, bind EA1 antigen, they would inherently possess the same cross-reactive properties.

Claim Rejections - 35 USC § 102/103

9. Claims 66, 68 and 70-85 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ezzell et al. (Infection and Immunity. Feb. 1988. 56(2): 349-356).

Ezzel et al teach isolated antibodies to, **EAI**. The major cell antigen to which the isolated antibodies bind in the Ezzel reference is 100% identical to the EAI protein disclosed by Applicants and set forth in SEQ ID NO: 1. Quantitation of antibody titers to EA1 in sera from guinea pigs was accomplished through ELISA (see page 351, column 1). The assays performed with the EA1 antibodies anticipate the method of claim 64 as they include contacting an antibody/fragment with a sample, forming a complex and detecting said complex. Indirect immunofluorescence assays are also taught. Vaccine trials were performed with EA1 and antibodies to EA1 were measured. Mouse monoclonal antibodies to EA1 are also taught. See page 355, column 1, halfway down the page. Ezzel et al teach that antibodies to EA1 bound to both B.anthracis strains carrying the pXO1 toxin plasmid as well as cured strains, whereas EA2 only bound to strains which carried the plasmid.

Applicants have disclosed in the instant specification that antibodies directed against this EAI protein are antibodies which bind to B.anthracis, but do not bind to B.thuringiensis, B.cereus, B.globigii and B.lichenformis. These antibodies are disclosed as the preferred embodiment in the instant specification. Although the reference does

not specifically recite that the antibody to B.anthracis does not specifically react with B.thuringiensis, B.cereus, B.globigii and B.lichenformis, it inherently would not since the antigen to which it binds is specific to B.anthracis and the instant specification supports this finding. The antibodies to the EAI protein would be identical to Applicant's antibodies to the EAI antibody, i.e., the antibodies are raised against the same antigen. There are no structural differences between the prior art antibody, e.g., specifically binds EA1 antigen of B.anthracis, and those that are instantly claimed. The intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition; e.g., does not bind *B.thuringiensis* or *B.cereus*, *B.globigii* and *B.lichenformis*. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. An antibody produced from the hybridoma deposited as PTA-2632 would also possess the same binding capabilities as the monoclonal antibodies taught by Ezzel, absent evidence to the contrary. Claim 78 is a product-by-process claim. .

Since the Patent Office does not have the facilities for examining and comparing Applicant's antibody with the antibody of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibody of the prior art. See

In re Best, 195 USPQ 430, 433 (CCPA 19&&). Since the instant kit claims do not require any components other than the antibodies, the reference anticipates the claims. The phrase "diagnostic kit" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include the antibody of Ezzel in a kit because kits comprising antibodies for use in bacterial detection assays were very well known in the prior art at the time the invention was made and the motivation for providing the reagents in kit would have been commercial as well as for ease in having all of the reagents present in one place.

Response to Applicants' Arguments:

Applicants argue that Ezzel et al do not disclose or suggest a monoclonal antibody and therefore cannot be applied as prior art against the claims. These arguments have been fully and carefully considered but are not deemed persuasive. Mouse monoclonal antibodies to EA1 are also taught by Ezzel et al. See page 355, column 1, halfway down the page, e.g.:

"[I]n current studies with mouse Mab to EA1, we have shown that Ames strain cells from blood agar cultures are stained in a manner identical to that of sera from guinea pigs vaccinated with the guanidine extract. The EA1 Mabs also intensely stained the residue that was left on the sides following cell detachment, thereby providing additional evidence that EA1 is a surface antigen of non-encapsulated cells".

11. Claims 67 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ezzell et al. (Infection and Immunity. Feb. 1988. 56(2): 349-356) as applied to claims 66, 68 and 70-85 above, and further in view of Loomis et al (WO 99/64863).

The teachings of Ezzell et al are set forth above. However, they do particularly exemplify the use of these antibodies in a colloidal particle based lateral flow detection system.

Loomis et al teach that colloidal gold particle immunoassays have been successfully used in the prior art for many years. See pages 1-3. Loomis et al teach a more sensitive immunoassay test to what was known in the art. It is a colloidal colorimetric flow through and lateral flow assay. The entire test is conducted on a test strep and the detection antibody is preferably a FAB fragment that has been labeled with a 5O-100mm gold particle and immobilized on a test pad. See page 4. It is taught that the use of capture dendrimers to align and secure capture antibodies on a solid surface insure that no immunological activity of the capture antibody is sterically hindered. Loomis claims the assay as a "test system".

It would have been prima facie obvious to one of ordinary skill in the art to use the antibodies taught by Ezzel et al in a colloidal lateral flow detection system as taught by Loomis et al to detect B.anthracis because Ezzel et al teach that the antibodies are highly specific to B.anthracis and that EAI constitutes the main lattice of the B.anthracis S-layer, and is the major cell-associated antigen. One of ordinary skill in the art would have a reasonable expectation that a specific antibody developed against the major cell-associated antigen of a bacterium to be very effective in detecting the bacterium in

a sample. Loomis et al teaches that it is a highly sensitive detection assay which is simple, sensitive and specific. The use of the EAI antibodies taught by Ezzel et al in a colloidal lateral flow detection system would have been obvious as a B.anthracis detection system. The assembly of the reagents to these assays in a diagnostic kit would have been obvious to one of ordinary skill in the art at the time the invention was made for convenience and storage capabilities. Loomis claims the assay as a "test system". It would have been obvious to one of ordinary skill in the art at the time the invention was made that this test system, if not an actual kit itself, could have been assembled as a kit because kits comprising detection assays were very well known in the prior art at the time the invention was made and the motivation for providing the reagents in kit would have been commercial as well as for ease in having all of the reagents present in one place.

Status of Claims:

12. No claims are allowed. Applicants have been arguing distinct and unexpected antibodies, yet those antibodies are not claimed. The antibodies instantly claimed do not structurally differ from those taught in the prior art. If Applicants can demonstrate that an antibody generated from their hybridoma is structurally different from that known in the prior art, then the antibody made from the hybridoma should be claimed- along with specific evidences filed to demonstrate it is unique from that of the prior art. The specification appears to indicate, at the top of page 14, that the exact location of the epitope which the claimed antibodies bind was not known at the time the invention was made.

13. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

J Graser 12/18/06

Jennifer Graser
Primary Examiner
Art Unit 1645